



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Food and Drug Administration  
Florida District  
555 Winderley Place, Suite 200  
Maitland, FL 32751

Telephone: 407-475-4700  
FAX: 407-475-4769

**VIA FEDERAL EXPRESS**  
**AND**  
**FACSIMILE 1-800-860-4326**

**WARNING LETTER**

**FLA-06-30**

August 9, 2006

Joseph Capper, CEO  
CCS Medical  
14255 - 49<sup>th</sup> Street North  
Suite 301  
Clearwater, Florida 33762

Dear Mr. Capper:

On October 19-20, 2005, a U.S. Food and Drug Administration (FDA) investigator jointly with an investigator from Florida Department of Health inspected your facility, located at 615 South Ware Blvd., Tampa, Florida. This investigation documented serious violations of the Federal Food, Drug, and Cosmetic Act (FDCA). The inhalation products manufactured by your firm are drugs within the meaning of section 201(g) of the FDCA [21 U.S.C. § 321(g)], and are unapproved new drugs under section 505 of the FDCA (21 U.S.C. § 355). These drug products are also misbranded within the meaning of section 502 of the FDCA (21 U.S.C. § 352).

FDA regards traditional pharmacy compounding as the combining, mixing, or altering of ingredients by a pharmacist in response to a physician's prescription to create a medication tailored to the needs of an individual patient. Traditional compounding typically is used to prepare medications that are not commercially available, such as medication for a patient who is allergic to an ingredient in a mass-produced product, or diluted dosages for children. It involves providing a service in response to a physician's prescription to accommodate the specialized medical needs of a particular patient. See *Thompson v. Western States Med. Ctr.*, 535 U.S. 357, 360-61 (2002):

All compounded prescription drugs are "new drugs" within the meaning of the FDCA. When a pharmacist compounds a prescription drug, by definition, he or she creates a new drug under federal law because the compounded product is not "generally recognized, among experts . . . as safe and effective." See 21 U.S.C. §§ 321(p); *Prof'l's & Patients for Customized Care v. Shalala*, 56 F.3d 592, 593 n.3 (5th Cir. 1995) ("Although the [FDCA] does not expressly exempt 'pharmacies' or 'compounded drugs' from the new drug . . . provisions, the FDA as a matter of policy has not historically brought enforcement actions against pharmacies engaged in traditional compounding."); *In the Matter of Establishment Inspection of: Wedgewood Village Pharmacy, Inc.*, 270 F. Supp. 2d 525, 543-44 (D.N.J. 2003), *aff'd*, *Wedgewood Village Pharmacy v. United States*, 421 F.3d 263, 269 (3d Cir. 2005) ("The FDCA contains provisions with explicit exemptions from the new drug . . . provisions. Neither pharmacies nor compounded drugs are expressly exempted."); *Weinberger v. Hynson, Westcott & Dunning*, 412 U.S. 619, 629-30 (1973) (explaining the definition of "new drug"). Under the FDCA, a

- The compounded metaproterenol 0.4545% is supplied in 3.3 ml and the commercially available product is 0.4% in 2.5ml vials.
- The compounded albuterol 0.0417% and 0.045% are supplied in 3 ml vials and the commercially available product is supplied as 0.042% in 3 ml vials;

For the purpose of the agency's exercise of its enforcement discretion, the availability of different size vials is not a meaningful distinction between your products and the commercially available products. Further, with respect to those products that are essentially copies of the commercially available products, we are not aware of any legitimate medical need for the insignificant variation of the formulation for each individual patient. This concern is especially true given the large volume of these products that you produce, as described below.

The inspection revealed that your firm manufactured/distributed approximately [REDACTED] vials of inhalation drug products within a 3 month period (July 2005 to September 2005). In addition, the batch size of your high volume products is large; for example, the batch size of the compounded Budesonide 0.0125% (0.25 mg) in 2 ml vials was [REDACTED] and was prepared every 10 to 30 days for the period between June and October, 2005. In light of the lack of medical need for these products, we do not believe that your firm's production volume is consistent with that of a traditional pharmacy compounding operation.

In light of the above, FDA will not exercise its enforcement discretion for your firm's manufacturing and distribution of these products. Your firms' compounded products are unapproved new drugs, and their introduction or delivery for introduction into interstate commerce violates sections 505(a) and 301(d) of the FDCA (21 U.S.C. §§ 355(a), 331(d)). Further, these compounded drugs are misbranded under section 502(f)(1) of the FDCA (21 U.S.C. § 352(f)(1)) in that their labeling fails to bear adequate directions for use and they are not exempt from this requirement under 21 C.F.R. § 201.115. These drugs are also misbranded under section 502(o) of the FDCA (21 U.S.C. § 352(o)) because they are produced in an establishment not duly registered under section 510 of the FDCA (21 U.S.C. § 360), and they have not been listed as required by section 510(j) of the AFDC (21 U.S.C. § 360(j)). Your facility is not exempt from registration and drug listing requirements under 21 C.F.R. § 207.10 and section 510(g) of the FDCA (21 U.S.C. § 360(g)) because it is engaged in the manufacture and distribution of drugs.

The above violations are not intended to be an all-inclusive list of violations at your facility. It is your responsibility to ensure that your facility complies with the Act and the applicable regulations. Federal agencies are advised of the issuance of all warning letters about drugs so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct all of the violations noted in this letter, and prevent their recurrence. Failure to promptly correct violations may result in regulatory action without further notice, including seizure and/or injunction.

Please reply in writing, within fifteen working days of receipt of this letter, stating the specific steps that you have taken to correct the noted violations, as well as the steps taken to prevent their recurrence. If corrective actions can not be completed within 15 working days, state the reason for the delay and the time within which corrections will be complete. Your responses will be reviewed and any corrective actions will be verified during our next inspection at your facility.

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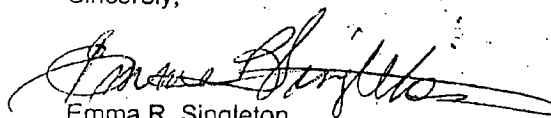
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Warning Letter No. FLA-06-30

Your reply should be directed to the U.S. Food and Drug Administration, to the attention of Shari H. Shambaugh, Compliance Officer, FDA, 555 Winderley Place, Ste. 200, Maitland, Florida 32751. If you have questions regarding this letter, please contact Mrs. Shambaugh at 407-475-4730.

Sincerely,

A handwritten signature in cursive script, appearing to read "Emma R. Singleton", written over a horizontal line.

Emma R. Singleton  
Director, Florida District